

REMARKS / ARGUMENTS

Claim 4 is currently under consideration in this application, but not included in any rejection. However, Applicants note that the Office action summary indicates that claims 1-6 are rejected, but the page 2 of the Office action indicates that rejections and/or objections not reiterated from previous office actions are withdrawn. Applicants request clarification of the status of claim 4.

Claims 1-3 and 5-6 were rejected under 35 USC 103(a) over Raza et al and Canepa et al in view of Dreys et al. Applicants request reconsideration of this rejection for the reasons that follow.

In order to reject claims under 35 USC 103, it is the PTO's burden to establish that the prior art would lead the skilled artisan to modify the prior art as required to arrive at the claimed invention and to have a reasonable expectation of success. In re O'Farrell, 7 USPQ2d 1673 (Fed. Cir. 1988) and DyStar Textilfarben GmbH v. C.H. Patrick and Co., 80 USPQ2d 1641 (Fed. Cir. 2006). See also, MPEP 2141, 2143, particularly 2143.01 and 2143.02. Therefore, it is the Examiner's burden to establish that the prior art suggests to substitute PTK787 for thalidomide in the method of treating MDS with a reasonable expectation success. Examiner has not alleged that the prior art teaches that PTK787 possesses cytoprotective and/or anticytokine properties similar to those of thalidomide. Therefore, in order to meet this burden, the Examiner must establish a nexus between thalidomide's utility for treating MDS and the antiangiogenic properties that PTK787 is alleged to share with thalidomide. Otherwise, the skilled artisan would not have a basis to reasonably expect PTK787 to share thalidomide's utility for treating MDS.

Applicants assert that Raza et al teaches that thalidomide's cytoprotective and/or anticytokine properties, and not its antiangiogenic properties, are believed to be the primary basis for its utility in treating MDS. At the first paragraph of the Discussion which begins on page 962, Raza et al teaches that thalidomide alleviated the cytopenias of some patients with MDS and further discloses that the reported study is the latest in a series of clinical trials conducted over 6 years using anticytokine and cytoprotective agents. At page 958, last sentence of the first paragraph of the Introduction, Raza et al discloses that substantial improvements in the cytopenias of some MDS patients resulted from attempts to suppress excessive cytokine-mediated apoptosis with cytoprotective and/or anticytokine therapies. Based on this disclosure, one of ordinary skill would most reasonably understand that Raza et al believed the reported improvement in the cytopenias of MDS patients to be due primarily to thalidomide's cytoprotective and/or anticytokine properties, and not due to its antiangiogenic

properties. Therefore, the references do not suggest a nexus between the antiangiogenic properties of thalidomide and its utility for treating MDS.

Applicants assert the references do not provide any suggestion or motivation for the skilled artisan to substitute PTK787 for thalidomide for the treatment of MDS. In addition, the references do not provide any basis for the skilled artisan to reasonably expect success when doing so. Therefore, the Examiner has failed to establish that the presently claimed invention is *prima facie* obvious over the cited references.

Applicants request withdrawal of the rejection of claims 1-3 and 5-6 under 35 USC 103(a) for the reasons discussed above.

Entry of this amendment and reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,



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